suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

§ 71.107 Package design control.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

(b) The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in

lieu of other verifying or checking processes, the licensee, certificate holder, and applicant for a CoC shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, certificate holder, and applicant for a CoC shall apply design control measures to the following:

(1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;

(2) Compatibility of materials;

(3) Accessibility for inservice inspection, maintenance, and repair;

(4) Features to facilitate decontamination; and

(5) Delineation of acceptance criteria for inspections and tests.

(c) The licensee, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval.

§ 71.109 Procurement document control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its contractors or subcontractors. To the extent necessary, the licensee, certificate holder, and applicant for a CoC shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.

§ 71.111 Instructions, procedures, and drawings.

The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining